

Oregon Jail MOUD Technical Assistance Team

EXTENDED-RELEASE BUPRENORPHINE (XR-BUP) IN JAILS IMPLEMENTATION GUIDE

Primary Contact:

J. Michael Winer, MD
Jail MOUD Program TA Lead
winerm@ohsu.edu

Secondary Contacts:

Dan Hoover, MD
Jail MOUD Program TA Director
hooverda@ohsu.edu

Emily Skogrand, Pharm. D
OHSU Addiction Pharmacist
skogrand@ohsu.edu

OHSU Jail MOUD Technical Assistance Team

The Oregon Health and Science University (OHSU) Jail Medication for Opioid Use Disorder (MOUD) Technical Assistance Team is funded by Oregon's Opioid Settlement Prevention, Treatment and Recovery Board. This document informs jails on the steps to obtain and store Extended-Release Buprenorphine injectable medications (XR-BUP). This document is not meant as clinical advice. As your jail is developing plans to obtain MOUD, including XR-BUP, we are available to help with technical assistance (TA). TA meetings can be utilized to help your team decide on evidence-based clinical protocols and dosing of products for your facility.



Injectable Extended-Release Buprenorphine in Jails

Extended-release buprenorphine (XR-BUP) is a novel formulation available as a weekly or monthly injectable medication to treat opioid use disorder (OUD).

There are currently two different formulations of XR-BUP available for consideration in jails.

Brand	Formulations	Administration	Storage
Sublocade	Monthly	Subcutaneous (under the skin injection)	Refrigeration required; may be stored for 12 weeks at room temperature.
Brixadi	Monthly & Weekly	Subcutaneous (under the skin injection)	No refrigeration required

What are the benefits of extended-release buprenorphine?

- Not treating opioid use disorder in incarcerated individuals causes people to have a reduced opioid tolerance and increases risk of overdose death upon release.
- Buprenorphine is an evidence-based medication for opioid use disorder that treats opioid withdrawal, opioid cravings, and reduces overdose death.
- Extended-release versions of buprenorphine reduces logistical barriers faced with daily medication dosing, reduces medical/security staff time, and improves the rate of follow-up into community treatment after release.
- In clinical trials, XR-BUP increased treatment retention in the community after release from jail when compared to sublingual (SL) buprenorphine:

- New York City jail releases: **69% of patients started on XR-BUP were still on treatment at 8 weeks** compared to **35%** retained in treatment at 8 weeks who were on sublingual (SL) buprenorphine.

Lee, J.D., Malone, M., McDonald, R., Cheng, A., Vasudevan, K., Tofighi, B., Garment, A., Porter, B., Goldfeld, K.S., Matteo, M., Mangat, J., Katyal, M., Giftos, J., Macdonald, R., 2021. Comparison of Treatment Retention of Adults With Opioid Addiction Managed With Extended-Release Buprenorphine vs Daily Sublingual Buprenorphine-Naloxone at Time of Release From Jail. JAMA Network Open 4, e2123032..

- Maine rural jail releases: Patients were approximately **3 times as likely to continue buprenorphine treatment** if started on XR-BUP while incarcerated compared to those started on SL buprenorphine.

O'Connor, A. B., et al. (2024). "Community buprenorphine continuation post-release following extended release vs. sublingual buprenorphine during incarceration: a pilot project in Maine." Health & Justice **12**(1).

What regulatory steps do I need to complete before ordering XR buprenorphine?

Requirement	Additional Information	Resources
DEA Licensing <input type="checkbox"/> Each jail provider must have a separate DEA license with the jail address practice site listed.	<ul style="list-style-type: none"> Each jail provider must have a separate DEA license with the address of the jail practice location where they are working. This will allow the provider DEA to order schedule III-controlled substances (buprenorphine) to be delivered to the jail. 	DEA license application : DEA form 224 <ul style="list-style-type: none"> Select your license type. <p>If any questions, you may call the NW Seattle office for inquiries: 571-387-3028.</p>

Requirement	Additional Information	Resources
REMS <input type="checkbox"/> Enroll in REMS program by submitting REMS Form. (Must have 1 per jail)	<ul style="list-style-type: none"> Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that is required for certain high-risk medications. XR-BUP REMS is to ensure that the medication is not directly dispensed to the patient but instead, administered by a healthcare provider. Any jail that intends to order Sublocade or Brixadi directly from an authorized distributor <i>must be certified</i> in the Sublocade or Brixadi REMS prior to purchasing. You must complete a separate REMS certification for each brand that you store on site. 	<p>Designate an Authorized Representative to oversee implementation and compliance with REMS program (Lead provider, nurse, or healthcare staff)</p> <p>The forms can be submitted online, faxed, or emailed.</p> <p>Sublocade:</p> <ul style="list-style-type: none"> Online REMS Form -Sublocade Fax- 1-866-823-9549 Email: certify@SublocadeREMS.com <p>Brixadi:</p> <ul style="list-style-type: none"> Online REMS Form- Brixadi Fax- 1-833-274-8597 Email: BRIXADIREMS@braeburnrx.com

Requirement	Additional Information	Resources
Storage System <input type="checkbox"/> Develop a system to store XR-BUP.	<ul style="list-style-type: none"> • Sublocade and Brixadi are a federal DEA schedule III-controlled substance and require special handling and storage. • XR-BUP should be kept in a locked cabinet within a locked medication room or locked refrigerator (Sublocade). DEA security requirements state “in a securely locked, substantially constructed cabinet” with limited access by office staff. (see next column) • Controlled substance medications require storage under two sets of locking mechanisms (double locked). – See examples in next column • The medication room is to remain locked at all time. 	<ul style="list-style-type: none"> • Security Requirements (Part 1301.72 section b) • Examples of two sets of locking mechanisms (double locked) <ul style="list-style-type: none"> ○ A locked box within a locked drawer or locked cabinet ○ A locked fridge behind a locked door ○ A locked cabinet behind a locked door
	<p>Sublocade requires refrigeration, but can be stored for up to 12 weeks unrefrigerated.</p> <ul style="list-style-type: none"> ○ <u>Of note</u>, 12 weeks unrefrigerated is a new storage option, and some packaging will still say that it must be refrigerated at all times. Please follow the storage directions on each package that you receive. ○ Sublocade should be stored in a refrigerator maintained between 2 to 8 degrees Celsius (36 to 46 degrees Fahrenheit) ○ Temperatures shall be monitored and logged on the Medication Refrigerator and Room Temperature Record maintained by your jail. ○ Temperatures should be checked on a business daily basis. 	
	<p>Brixadi does not require refrigeration.</p>	

Requirement	Additional Information	Resources
Medication Records <input type="checkbox"/> Develop a system for records and inventories of all controlled substances dispensed, including buprenorphine.	<ul style="list-style-type: none"> There are specific federal DEA record keeping requirements for providers who prescribe, store, and administer Schedule III controlled substances. Providers must keep records and inventories of all controlled substances dispensed, including buprenorphine <ul style="list-style-type: none"> Track medication received, medication administered, and do regular inventory verification (see example in next column). These protocols must be readily available if requested by the DEA. Two staff are required to sign the medication log when adding or removing Sublocade or Brixadi doses to/from the locked storage system. Best practice is for two licensed healthcare staff (e.g., 2 nurses or nurse + provider). If your facility has only one licensed healthcare staff on site, you can develop a policy of one licensed healthcare staff + one jail staff when two licensed healthcare staff are not available. This log must be kept for at least two years. Jails are also required to keep documentation of their protocols, practice guidelines or practice agreements readily available (see example in next column). The use of a separate medication administration record (MAR) is also strongly recommended when administering doses in your jail if you do not have an Electronic Medical Record (EMR). 	<ul style="list-style-type: none"> Code of Federal Regulations: Title 21- Chapter II -Part 1304 – Records and Reports of Registrants (National Archives and Records Administration 2023c) Example protocols, practice guidelines, and practice agreements. (Grayken Center – Page 19) Example inventory log (Grayken Center – Page 21)

Requirement	Additional Information	Resources
Destruction <input type="checkbox"/> Create a policy for On-Site Destruction of XR-BUP <input type="checkbox"/> Create an internal destruction of XR-BUP log <input type="checkbox"/> Maintain a destruction log using DEA Form 41 in addition to internal log	<ul style="list-style-type: none"> Jails should create a policy for destruction of On-site XR-BUP in the case that it is expired or not given to a patient (e.g., patient declines XR-BUP after it has been removed from packaging). The U.S. Drug Enforcement Administration requires the completion of DEA Form 41 to record controlled substance destruction. This form is only given to the DEA if they request it. This form must be kept and available for a minimum of two years in compliance with 21 U.S.C. 827. (see next column). 	<ul style="list-style-type: none"> Example On-Site Destruction of XR-BUP Policy (Grayken Center – Page 23) Example XR-BUP Internal Disposal log (Grayken Center- Page 22) DEA Form 41

Where do I purchase the injectable XR buprenorphine?

	Sublocade	Brixadi
<input type="checkbox"/> Find an authorized supplier and set up an account	<p>Full list of retailers: https://www.sublocaderems.com/#Main/Resources</p> <ul style="list-style-type: none"> • Cardinal Health • Henry Schein <p>The above retailers qualify for the MMCAP discount for corrections facilities. (see MMCAP discount section below)</p>	<p>Full list of retailers: https://www.brixadihcp.com/access-and-support/</p> <ul style="list-style-type: none"> • Cardinal Health • Henry Schein <p>The above retailers qualify for the MMCAP discount for corrections facilities. (see MMCAP discount section below)</p>
<p>Note: Cardinal Health</p> <ul style="list-style-type: none"> • Oregon's volume discount would apply through this retailer making these items an additional 5% - 7% cheaper. • Jails would also be able to purchase any other OUD medication as well since Cardinal Health is a full-scale pharmacy wholesaler. 		
<p>Once you choose a supplier, you will order using a controlled substance form provided by the supplier.</p>		

What is the cost of injectable XR buprenorphine?

Brand	Formulations	Dose	Discount		
			No Discount:	MMCAP program discount:	340B program:
Sublocade Sublocade manufacturer (Indivior) Contacts: Rachael Fisher, Access Director Criminal Justice Systems, Pacific Northwest OR/ID Phone: 503-200-9456 Email: Rachael.Fisher@indivior.com Diana Chinaea Email: diana.chinea@indivior.com	Monthly	300mg	\$2,016.52 /dose	\$1,572.89/dose	\$1400-1550/dose
		100mg	\$2,016.52 /dose	\$1,572.88/dose	\$1400-1550/dose

Brand	Formulations	Dose	Cost		
			No Discount:	MMCAP program discount:	340B program:
Brixadi Brixadi manufacturer (Braeburn) contact Jen Kuper Braeburn Northwest Regional Business Manager Email: jkuper@braeburnrx.com	Monthly	64 mg	\$1708/dose	\$1537.20/dose	\$1100-1300/dose
		96 mg			
		128mg			
	Weekly	8 mg	\$427/dose	\$384.30/dose	\$300-400/dose
		16 mg			
		24 mg			
		32mg			

MMCAP Discount Program

The Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP) is a free voluntary group purchasing organization that your jail can access to purchase reduce priced injectable XR-BUP. The State of Oregon, Department of Administrative Services has both agreements in place, so no additional procurement is needed.

The application is free here: <https://infuse-mn.gov/membership-application/index.jsp>

- A DEA number is not needed to set up the membership agreement. If you are in the process of obtaining a DEA number, you can still complete a membership application.
- Once in the application check “pharmaceutical wholesaler services”

Contact Oregon MMCAP Representative, **Kim Hankins**, can help your facility complete the necessary paperwork for an expedited and smooth implementation.

Email: kim.hankins@state.mn.us
Cell: 503-999-5013

340B Program

340B is a federal program that allows eligible hospitals or clinics to purchase medications at a reduced price. These entities generally provide healthcare to an underserved patient population, must meet federal requirements, and must have a contract with a certified 340B pharmacy. Savings from 340B discounts are reinvested and used for medical care. Jails often have difficulty accessing 340B pricing unless already affiliated with a pharmacy or FQHC obtaining 340B pricing.

SUMMARY JAIL IMPLEMENTATION OF XR-BUP CHECKLIST

- ☐ Apply for facility DEA license for Schedule III substances for each site
- ☐ Enroll in REMS program by submitting REMS Form (Must have 1 per jail)
- ☐ Enroll in MMCAP Infuse governmental group purchasing program
- ☐ Set up an account with a distributor (example: Cardinal Health)
- ☐ Develop a system to store XR-BUP at your jail
- ☐ Develop a system for records and inventories of XR-BUP
- ☐ Create a policy and internal destruction log for on-site destruction of XR-BUP